Cassava Audit Number: _A27__

Audit Report

Organization Audited:	The City College of New York (CCNY), School of Medicine Department of Molecular, Cellular, and Biomedical Sciences Center for Discovery and Innovation (CDI)
Address, Phone Number, and Website (if available):	CCNY CDI building 160 Convent Avenue New York, NY 10031
Point of Contact: *(Name, Title, and Email):*	Zhe Pei, Ph.D. Research Fellow topeizhe@hotmail.com Hoau-Yan Wang, Ph.D. Principal Investigator hoauyan@gmail.com

Audit Date(s):	Audit inquiry/document review: 11-18 Apr 2022 and 16-17 Aug 2022 On-site audit: 21-22 Sept 2022
Auditor(s):	Laura A. Rodriguez, Sr. Director of Clinical Quality Systems Michael Marsman, PharmD, SVP Regulatory Affairs
Audit Type:	☒ Vendor Qualification ☐ Study ☐ Site (Site #_____)
Protocol Number: (*If applicable*)	PTI-125-02
Project Name: (*If applicable*):	*A Phase 2b, Randomized, Double-blind, Placebo-controlled, Multiple Dose, Biomarker and Safety Study of PTI-125 in Mild-to-moderate Alzheimer's Disease Patients*

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Auditor(s):

Title	Name	Signature/Date
Sr. Director Clinical Quality Systems	Laura A. Rodriguez	DocuSigned by: Laura A. Rodriguez Signer Name: Laura A. Rodriguez Signing Reason: I am the author of this document Signing Time: 18-Oct-2023 | 14:52 CDT 593B48548E2E4CA7B2559CBECDE6911E
SVP, Regulatory Affairs	Michael Marsman, PharmD.	DocuSigned by: Michael Marsman, Pharm D Signer Name: Michael Marsman, Pharm D Signing Reason: I approve this document Signing Time: 18-Oct-2023 | 16:08 CDT 6252303FF961490FACFF567B84CF70BC

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I. EXECUTIVE SUMMARY

An onsite vendor qualification audit of The City College of New York School of Medicine (CCNY) was performed on 21-22 September 2022 by Cassava Sciences' (Cassava) Sr. Director of Clinical Quality Systems, Laura A. Rodriguez and SVP of Regulatory Affairs, Michael Marsman PharmD. An initial vendor audit inquiry to review CCNY quality management documentation was also performed on 11-18 April and 16-17 Aug 2022 to verify if the laboratory had the necessary quality documents and practices in place in accordance with cGLP guidance relevant to the research work being conducted.

The purpose of the audit and audit inquiry was to assure Cassava that CCNY has adequate facilities, resources, processes, and a quality management system in place to perform biomarker analysis and research services for Cassava's clinical studies and to ensure the work performed complies with relevant regulations and guidance documents. Though the contract with CCNY stated the work was not subject to cGLP requirements it was expected that the facility would perform the contracted work according to sound scientific principles, many of which are also cGLP requirements, in compliance with CCNY Medical School standard operating procedures (SOPs) with review by supervisory technical staff.

The following regulatory and guidance documents, were used as references for the audit and for identifying non-conformance for observations found (***See Attachment A***):

- 21 CFR Part 11, *Electronic Records; Electronic Signatures*
- 21 CFR Part 50, *Protecting of Human Subjects*
- *21 CFR Part 58, Good Laboratory Practices for Nonclinical Laboratory Studies*
- ICH E6 R2, *Good Clinical Practice: Integrated Addendum to ICH E6 (R1)*
- *Guidelines for Human Biospecimen Storage, Tracking, Sharing and Disposal within the NIH Intramural Research Program*

II. AUDIT OVERVIEW

An initial vendor audit inquiry to review CCNY quality documentation was performed on 11-18 Apr 2022 and 16-17 Aug 2022 by email (***See Attachment B***). The questions sent were transferred to a word document by Dr. Zhe Pei (***See Attachment C***) who assisted in responding to the requested information. This document was utilized to provide responses by both CCNY and the CSI auditor. This initial inquiry was to determine if CCNY had the minimum quality documents and processes in place to support biomarker analysis and research since their contract did not require them to be cGLP compliant. During this time, obtaining the requested information was difficult due to Dr. Pei's and Dr. Wang's academic schedule. Over the course of a few months, Dr. Pei sent the following documentation for review:

- Audit Inquiry Responses
- Certificate of Analysis for many reagents
- Dr. Pei GCP Training Record

Upon review of the documentation and responses provided by Dr. Pei from April to August 2022, it was determined that a formal on-site audit was needed to fully review the CCNY School of Medicine's processes, procedures, and quality documentation that were in place as there were many deficiencies identified with the initial information provided.

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On 19 September 2022, an impromptu on-site audit was scheduled with Dr. Hoau-Yan Wang and Dr. Zhe Pei to be conducted 21-22 Sept 2022. This was scheduled as a result this auditor's preliminary findings from the initial audit inquiry/document review and an FDA inspection of the laboratory on 14-16 Sept 2022. Due to the audit being scheduled so quickly, a formal agenda was not created.

The onsite audit began with an opening meeting on 21 September 2022, where the audit objectives and purpose were discussed with the CCNY Representatives. The following were present for the opening meeting:

- Dr. Hoau-Yan Wang, Principal Investigator (CCNY)
- Dr. Zhe Pei, Research Fellow (CCNY)
- Dr. Michael Marsman, SVP Regulatory Affairs (Cassava Sciences)
- Ms. Laura A. Rodriguez, Sr. Director Clinical Quality Systems (Cassava Sciences)

The audit consisted of a tour of the laboratory, interviewing Dr. Wang and Dr. Pei, and an extensive review of the laboratory's equipment calibration and maintenance records, sample management to include sample storage and tracking, sample shipping manifest forms, ELISA and Western Blot reagents certificate of analysis, personnel training records, and study records.

The close out meeting was held on 22 September 2022 to discuss the audit and any observations identified. Present for the close out meeting were the following:

- Dr. Hoau-Yan Wang, Principal Investigator (CCNY)
- Dr. Zhe Pei, Research Fellow (CCNY)
- Dr. Michael Marsman, SVP Regulatory Affairs (Cassava Sciences)
- Ms. Laura A. Rodriguez, Sr. Director Clinical Quality Systems (Cassava Sciences)

The audit resulted in **5** critical observations **2** major observation, **1** minor observations, and **0** comments. The observations and comments are documented at the end of the report in **Attachment A: *Audit Observation Report***.

Observations noted during the audit are categorized based on risks the observations may have to the study. Observations are classified into four categories: critical, major, minor, and comments.

- Critical: Observed conditions, practices, or processes that adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data. Critical findings could be a combination of major deficiencies which indicate a serious systemic failure. Critical deficiencies require immediate action.
- Major deficiency: Observed conditions, practices or processes that might adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of cGLP principles.
- Minor deficiency: Observed conditions, practices or processes that would not be expected to adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data.
- Comments: A suggestion (not a cGLP deficiency) for possible improvement to a current process, procedure, operation, and/or quality system.

All the observations were reviewed with the CCNY representatives. Recommended corrective actions were discussed at the time of the meeting as well in a follow up email sent on 28

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September 2022. This email highlighted those corrective actions that needed to be addressed immediately (***See Attachment D***)

III. CONCLUSION:

Vendor qualification is determined based on the audit results and overall cGLP compliance. One of the following ratings is then assigned to the vendor depending on the results found:

- Acceptable Rating: Vendor meets a standard of general compliance to cGLPs that may include some major and minor observations.
- Marginal Rating: Vendor meets a standard of marginal compliance to cGLPs and/or determination of deterioration in compliance was found based on the major and/or minor observations noted.
- Unacceptable Rating: Vendor has a deficient standard of compliance with cGLPs and/or a determination of absence of controls/systems was found based on the critical, major, and/or minor observations noted. Facility warrants serious quality or compliance concerns.

Based on the lack of procedures, proper documentation practices, equipment and freezer qualification, and software access control, CCNY School of Medicine was found to not have all the required processes in place at this time to support the biomarker analysis and research services in a cGLP complaint setting. Again, though cGLP compliance was not required as part of their contract, the work was to be performed according to sound scientific principles in compliance with their SOPs which they lacked. The biggest concern for this auditor was also the lack of proper documentation practices. As a result, CCNY is considered **unacceptable** and **temporarily not qualified** to provide biomarker analysis and research services for any future Cassava studies. A temporary not qualified rating was issued as the laboratory began correcting many of observations noted during the audit. However, until all are in place and a follow-up audit is conducted to confirm the observations have been closed out, they should not be contracted for any further biomarker analysis and research work.

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IV. AUDIT DETAILS

1.0 Organizational Overview and Facilities

Dr. Wang operates independently within the school when it comes to research projects with Dr. Pei and an assistant helping him. There is no formal organizational structure as this is an educational institution. However, Dr. Pei did create an organizational chart that listed the internal laboratory structure (***See Attachment C*** - question 5).

Security to the building is tight with entrance only being allowed by being buzzed in by armed security officers where one passes through metal detectors. To continue to enter the building, one must show proof of Covid vaccination, wear a mask, and be escorted at all times.

The laboratory is located on the second floor of the building and is equipped with key card access. The freezers and refrigerators are located in the hallway outside of the laboratory areas and are locked. The laboratory area was found to be very congested and not very organized. There were many reagents that were expired within the laboratory. Pipets were stored on a pipet rack; however, there were some sitting on the bench. The weighing room where the balances were located was clean but also very congested.

2.0 Regulatory Inspection History:

CCNY recently went through an FDA inspection on 14-16 Sept 2022 where a 483 was issued. Response to the 483 was pending at the time of the audit.

3.0 Standard Operating Procedures:

The auditor noted there wasn't an SOP index nor enough SOPs in place for the work that was being conducted within the laboratory with the exception of the following:

- Pipet Calibration,
- CSF Sample Handling
- Determination of albumin in CSF and plasma for BBB integrity
- Determination of IgG in CSF and plasma for BBB integrity

These four SOPs were not well written, in a formal template, or contained an approval signature. A recommendation was provided to create one for each operation they performed within the laboratory utilizing a formal template and having an approval signature.

4.0 Equipment Records:

Equipment calibration and maintenance records were either out of date or did not exist with the exception of the pipets and balances which had current calibration certificates at the time of the audit. Essential equipment such as the FilterMax F5 (ELISA) and -80℃ freezer monitor had not been calibrated in several years. Upon further inquiry, the auditors learned that the instrument and freezer had not been validated/qualified prior to sample analysis and sample storage.

During the audit, Dr. Pei indicated the FDA had asked to see the freezer log, but she was not able to access it and told them she did not think one existed. This auditor was able to find the freezer log and confirm there is one in place that dated back from the day the freezer was installed. The

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auditor also confirmed there had been no freezer excursions at the time the PTI-125-02 and PTI-125-04 study samples were stored at the CCNY laboratory.

5.0 Training Records:

Training certificates for the three department staff were provided and found to be in order with regards to the training required for working on clinical trials. Though a formal training report was not provided, the auditor was shown a training record through the University portal for Dr. Pei.

6.0 Information Technology:

While inquiring about audit trails and history of the ELISA software and freezer, the auditor was informed that the ELISA computer being utilized was not the original computer as the previous one had been stolen. Due to this, there was no password protection to the system and/or the FilterMax F5 software though a request to update the system to provide access control had been requested through the university IT department for over a year. During the FDA inspection, the inspectors noted there was not an audit trail for the PTI-125-02 sample analysis and the system lacked one; however, this auditor was able to locate the audit trail and confirm there is one present for the PTI-125-02 sample analysis.

7.0 Study Records:

In reviewing the sample inventory, tracking, and chain of custody for PTI-125-02, the auditor noted there was no formal process and all samples for every Cassava study were grouped into one spreadsheet. Sample manifest forms were also bound together in one binder. The auditor recommended the separation of the samples within the inventory log and place each study manifest into separate binders.

Also noted was there was no formal log book entry of the experiments performed to include the pipets IDs used with calibration due dates, lot numbers and expiry dates for reagents used, when samples were received and returned, lot numbers for the ELISA and Western blot kits used, and preparation of calibration curves and/or QCs (noted later there were no QCs utilized).When discussed with the CCNY representatives, The auditor was provided with some information on what reagent and kits were used including lot numbers but there was no organization of this information. A recommendation was made to create study folders within their server with subfolders for each element to store the CoAs, calibration and maintenance certificates, and create an excel log to document the information they have with regards to lot numbers and expiry dates. Also suggested was to institute paper or electronic logbooks for all experiments going forward to include keeping a separate logbook for each study or project.

8.0 Audit Summary

CCNY School of Medicine Laboratory was found to not have all the required processes in place at this time to support the biomarker analysis and research services. They lack standard operating procedures, proper good documentation practices, and laboratory practices (i.e., equipment calibration and sample management) that are deemed critical for conducting any type of analysis to support a clinical trial. They are considered **unacceptable** and **temporarily not qualified** to provide biomarker analysis and research services for any future Cassava studies.

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ATTACHMENT(S)

- Attachment A: Audit Observation Report.
- Attachment B: CSI Audit Inquiry Email
- Attachment C: CCNY_CSI Response to Audit Inquiry
- Attachment D: Audit Corrective Actions Email

CASSAVA sciences

Attachment A
Audit Observation Report

Observation #	Records Reviewed	Category	Observation	Non-compliance	Severity	CAPA Required	Recommendation(s) / Comment(s)
1	SOPs	Deficient Process or Procedure	The laboratory did not have any formal SOPs in place. The four SOPs provided were not well written, did not contain an approval signature, and were not in a formal template.	Lack of process and procedures in place for the work being performed.	Critical	Yes	Create SOPs in a formal template with an approval signature for all the work being performed in the laboratory. This includes sample management and good documenation practices.
2	Study Records	Deficient Process or Procedure	Lack of experiment logbooks/notebooks for all study/research work being performed.	Good documenation practices.	Critical	Yes	Institute logbooks for all experiments (suggest one for ELISA and Western Blot). Keep a separate logbook for each study you are working on. The logbooks will need to document the following information for each experiment ensuring at the end the pages are signed and dated: a.Name of Person(s) performing the experiment b.Date c.Study number d.Experiment Name e.Lot numbers of all chemicals and materials used along with the name of the item f.List of samples or reference to the file that list the sample being tested g.Documentation of experiment performed
3	Study Records	Deficient Process or Procedure	Lack of study record organization which makes it difficult to recreate what was used during sample analysis (i.e., reagents, ELISA and Western Blot kit lots, pipets, -80C freezer, and balances). All documents provided were either on a network drive, in a binder, or loose in a folder.	Good documenation practices.	Critical	Yes	Recommend creating specific folders on your network drive. These folders include the following information: a.Chemicals and Materials i.COA ii.SDS iii.Spec Sheets b.Correspondence_Emails (if study related) c.Equipment i.Balance 1.Calibration 2.Verification checks ii.-80 Freezer 1.Calibration 2.Freezer logs iii.Multimode Detector 1.Calibration iv.Pipets 1.Calibration 2.Verification checks d.Samples List_Manifest (if study related) For all Cassava Science related work, we are requesting you create a higher-level folder for each study that contains this information.
4	Equipment Records	Deficient Process or Procedure	Essential equipment such as the FilterMax F5 (ELISA) and -80°C freezer monitor had not been calibrated in several years due to Covid.	Calibration and maintenance of critical laboratory equipment.	Critical	Yes	Recommend contracting an outside vendor to immediately calibrate and service the FilterMax F5 and -80C freezer monitor.
5	Equipment Records	Deficient Process or Procedure	The -80°C freezer had not been qualified/validated prior to sample storage of study samples.	Failure to perform IQ/OQ/PQ of critical laboratory equipment.	Critical	Yes	Recommend contracting an outside vendor to immediately qualify the -80C freezer.
6	Software - access control	Deficient Process or Procedure	The ELISA computer being utilized was not the original computer as the previous one had been stolen. Due to this, there was no password protection to the system and/or the FilterMax F5 software.	IT Security	Major	Yes	Establish user login and password for the computer and for accessing the FilterMax F5 software.
7	Study Records	Deficient Process or Procedure	There was no formal process for sample inventory, tracking, and chain of custody for PTI-125-02 samples. All three studies had their samples grouped into one inventory spreadsheet. Sample manifest forms were also bound together in one binder.	Proper sample management	Major	Yes	Recommend the separation of the samples within the inventory log per study by creating separate tabs/spreadsheet for each study and placing each study's manifest into separate binders.
8	Facilities	Deficient Process or Procedure	The laboratory was very congested and not very organized. There were many reagents that were expired within the laboratory. Some pipets were sitting on the bench. The weighing room where the balances were located was clean but also very congested.	Possiblity of cross contamination and use of expire reagents.	Minor	No	Having a cluttered laboratory and pipets sitting on benches presents itself as being unclean and increases the risk of cross contamination. Recommend cleaning the labratory up and staging pipets in their rack. Though documentation that was finally received regarding the reagent and kit lots used for the study analysis demonstrated expired reagents were not used, having expired reagents within a laboratory increases the risk of their use. Recommend seperating these into a non-GLP section to avoid use during study sample analysis.

Attachment B: CSI Audit Inquiry Email

From: Laura Rodriguez
To: Zhe Pei
Subject: RE: Audit information
Date: Monday, April 11, 2022 1:26:00 PM
Attachments: image001.png

Hi Zhe,

I am available Friday, April 15th from 9-10:30 am and 1-4 pm central time. After that, I won't be available again until the week of April 25th as I am out of town next week performing an audit. In the meantime, here is a list of some of the documents that would be requested for review:

- Current Index that list the SOPs/Work Instructions/ Guides/Plans for your laboratory, so we know what is currently in place
- Business continuity and disaster recovery plan
- Regulatory agency and/or accrediting body inspection summaries for ~past 5 years
- Current certificates of accreditation
- Organizational chart for the lab
- Listing of computerized systems to include validation status
- Data review flow chart (if not in an SOP)
- COA for reagents and antibody kits being used to include expiration date and retesting if performed
- Calibration and maintenance documentation for all equipment used for AD biomarker analysis
- Equipment files relative to refrigerator and freezers for sample and reagent storage to include temperature mapping and control
- Backup generator maintenance records
- Training records for the staff involved in the validation of the method and sample analysis
- Validation documentation for software used for AD biomarker analysis and data handling (ensuring part 11 compliance as well)
- Validation of AD biomarker method (p-Tau181 and any other biomarker have been analyzed for our studies)
- Validation documentation for all equipment used for AD biomarker analysis to include balances and pipets used for any reagent preparation

Please feel free to reach out to me if you have any questions prior to us meeting.

Thank you,

Laura

Laura A. Rodriguez
Director, Clinical Quality Systems
Cassava Sciences, Inc.
7801 N. Capital of TX HWY
Suite 260

Austin, TX 78731
Office: 512-501-3179 / Mobile: 765-505-0301
lrodriguez@cassavasciences.com

From: Zhe Pei <topeizhe@hotmail.com>
Sent: Monday, April 11, 2022 1:05 PM
To: Laura Rodriguez <lrodriguez@cassavasciences.com>; Lindsay Burns <lburns@cassavasciences.com>
Subject: Re: Audit information

Hi Laura,

Thanks for the e-introduction from Lindsay!
I am currently working with Prof. Wang in CUNY, New York. May I ask if I could book an appointment with you to go through the auditing procedure & documentary works through the phone? I just want to start asap in order to be prepared.

Thank you!

Zhe

From: Lindsay Burns <lburns@cassavasciences.com>
Sent: Monday, April 11, 2022 12:58 PM
To: Laura Rodriguez <lrodriguez@cassavasciences.com>; Zhe Pei <topeizhe@hotmail.com>
Subject: RE: Audit information

Hi Laura,

I'm copying Zhe here so you can connect. Thanks!

Lindsay

From: Laura Rodriguez <lrodriguez@cassavasciences.com>
Sent: Monday, April 11, 2022 12:57 PM

To: Lindsay Burns <lburns@cassavasciences.com>
Subject: Audit information

Hi Lindsay,

Please send me the contact information for Zhe so I can start communicating with her.

Thank you,

Laura

Laura A. Rodriguez
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1. Current Index that list the SOPs/Work Instructions/ Guides/Plans for your laboratory, so we know what is currently in place

Zhe Response: Standard Operating Procedures (SOPs) for Labs: lab safety regulatory (Please see the university lab safety requirements)

CSI Response: We need your procedures that tell the following:

- Protocol of how you conduct all laboratory processes
  - To include running or preparing calibration
  - Data processing
- Lab safety protocols

2. Disaster recovery plan

Zhe Response: Do you mean the contact information of all lab members?

CSI Response: This document tells how the university or building responds to a loss of power, natural disaster, loss of network server, etc.

3. Regulatory agency and/or accrediting body inspection summaries for ~past 5 years

Zhe Response: Couldn't find any lab regulation form, may need the template to create one

CSI Response: In speaking with Zhe, per her knowledge they have never been audited.

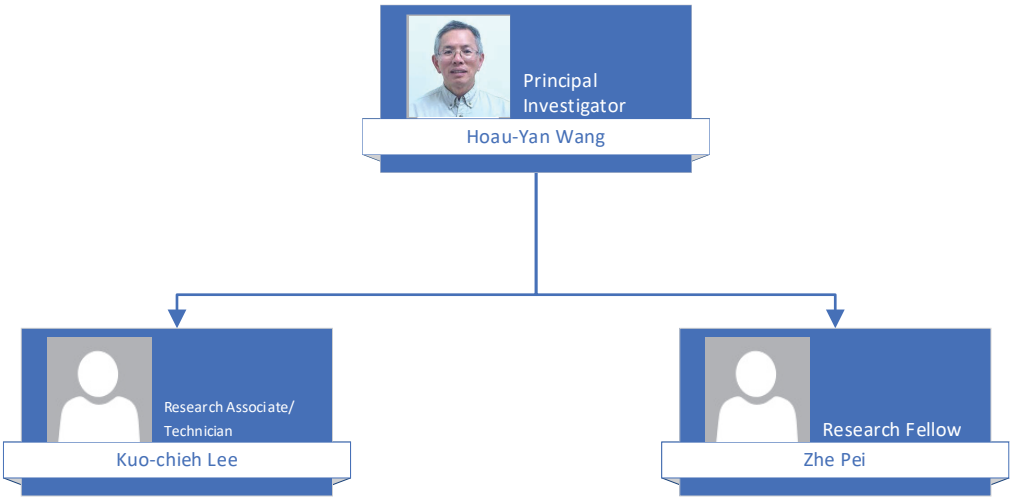
4. Current certificates of accreditation

Zhe Response: Not a GCL certificate lab.

CSI Response: Dr. Wang lab is a research lab thus does not have an accreditation from CLIA or CAP lab, so not applicable.

5. Organizational chart for the lab

Zhe Response: Zhe provided chart below.



CSI Response: Please ensure this is formalized with a revision date.

6. Listing of computerized systems to include validation status

Zhe Response: No Lab LAN available. Would you please let me know which part of the CS we need to record?

CSI Response: Instrument software

7. Data review flow chart (if not in an SOP) :

Zhe Response: N/A, because all results were forward to statisticians for further processes; we did not analyze data in this lab.

8. Certificate of Analysis (COA) for reagents and antibody kits being used to include expiration date and retesting if performed

Zhe Response: COA forms have been downloaded/requested from vendors.

CSI Response: Acknowledge receipt of documents you sent but you need to file them within your lab/network drive

9. Calibration and maintenance documentation for all equipment used for AD biomarker analysis

Zhe Response: Most lab equipment's should be covered by the maintenance plan of the University. Need to request for their documentations.

CSI Response: Yes, need to have in place calibration records for all pipets, freezer temperature recorders, instruments.

10. Equipment files relative to refrigerator and freezers for sample and reagent storage to include temperature mapping and control

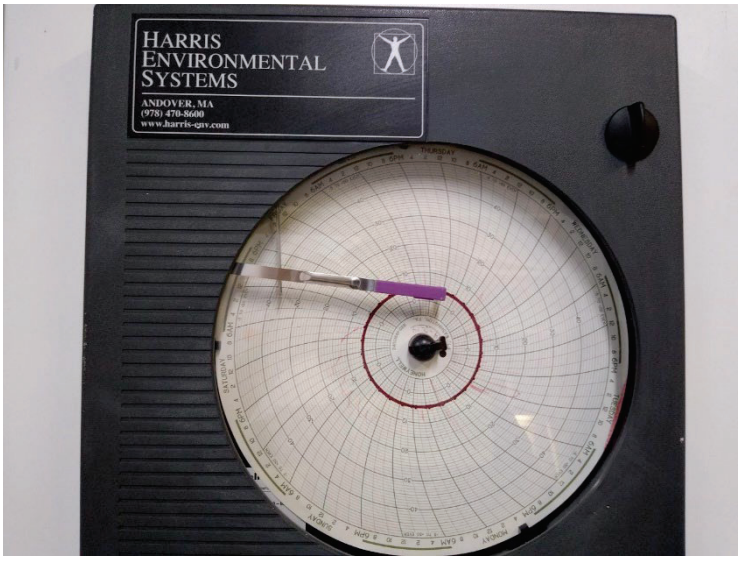
Zhe Response: Per Zhe, not sure what records are needed. Did some information for freezers.

CSI Response: You need to have the following in place and readily available for inspection:

- Need temperature Log
- Need Calibration record
- Tag freezers with calibration date

Zhe Response: The cold room temperature mapping:

CSI Response: Need to change out the charts and archive them for confirmation of no temperature excursions



Zhe Response: The -80C freezer only has temperature alert/monitor but don't have a record. May need to get extra sensors to make the record.

CSI Response: Please see if the alert/monitor is storing data any where and if it can be retrieved.

11. Backup generator maintenance records

Zhe Response: All -80°C freezers are connected to the Backup Power for the Laboratory of the building. Need to contact the maintenance department to get their maintenance records.

CSI Response: Yes, need to get maintenance records and records of testing of generator.

12. Training records for the staff involved in the validation of the method and sample analysis

Zhe Response: Per Zhe, does not have copy of these.

CSI Response: Have University HR print out your, Dr. Wang, and Kuo-Chieh Lee's taining record.

13. Validation documentation for software used for AD biomarker analysis and data handling (ensuring part 11 compliance as well)

Zhe Response: Per Zhe, they do not have any software operating instrumentation for biomarker analysis.

CSI Response: Okay for instrumentation as it does not apply. However, still need validation on statistical software used for analysis.

14. Validation of AD biomarker method (p-Tau181 and any other biomarker have been analyzed for our studies)

Zhe Response: Per Zhe, they do not have this as it is an out-of-the box kit that they use.

CSI Response: Then please have available the following information from vendors:

- Technical data sheet
- Manual of Elisa Kit you are using and antibody

15. Validation or qualification documentation for all equipment used for AD biomarker analysis to include balances and pipets used for any reagent preparation

Zhe Response: Per Zhe, they do not have this information but have calibration records.

CSI Response: Then please have available the following records:

- Calibration records for pipets
- Calibration record for balances (if used)

Attachment D: Audit Corrective Actions Email

Laura Rodriguez

From: Laura Rodriguez
Sent: Wednesday, September 28, 2022 7:30 AM
To: Hoau-Yan wang; Zhe Pei
Cc: Michael Marsman; jennifer.beidel@saul.com; Guy D. Singer (gsinger@orrick.com)
Subject: Corrective Actions from my Audit
Attachments: CUNY CDI SOP Template.docx

Good afternoon,

Thank you both for all your help last week and yesterday. As discussed last week as part of my audit, I am recommending/requesting the following immediate corrective actions be put into place:

1. Institute logbooks for all experiments (suggest one for ELISA and Western Blot). Keep a separate logbook for each study you are working on. The logbooks will need to document the following information for each experiment:
    a. Name of Person(s) performing the experiment
    b. Date
    c. Study number
    d. Experiment Name
    e. Lot numbers of all chemicals and materials used along with the name of the item
    f. List of samples or reference to the file that list the sample being tested
    g. Documentation of experiment performed

    Upon filling/completing a page, sign and date the page at the bottom. If the experiment goes to a next page add "continued from page #".

2. SOPs are going to be formalized in a template. I have created one you can use or use it as a reference for a shorter / different one.

3. Create specific folders on your network drive. These folders include the following information:
    a. Chemicals and Materials
        i. COA
        ii. SDS
        iii. Spec Sheets
    b. Correspondence_Emails (if study related)
    c. Equipment
        i. Balance
            1. Calibration
            2. Verification checks
        ii. -80 Freezer
            1. Calibration
            2. Freezer logs
        iii. Multimode Detector
            1. Calibration
        iv. Pipets
            1. Calibration
            2. Verification checks
    d. Samples List_Manifest (if study related)

For all Cassava Science related work, we are going to request you create a higher-level folder for each study that contains this information.

We can expand on this further, but this is what I am proposing as an immediate corrective action to get you in compliance with Good Laboratory Practices and Good Documentation Practices standards. I will write everything up in a formal vendor audit report to you but in the meantime, please start working on implementing these corrective actions.

Please reach out if you have any questions.

Thank you,

Laura

Laura A. Rodriguez
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Envelope Id: 0C29B8CF4A4E486CBAC0FA0A9350A6BB
Status: Completed
Subject: Complete with DocuSign: F-106.0 Audit Report_CCNY_21-22 Sept 2022_final.pdf
Source Envelope:
Document Pages: 18
Signatures: 2
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-06:00) Central Time (US & Canada)

Envelope Originator:
Laura A. Rodriguez
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IP Address: 71.41.248.226

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Status: Original
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Holder: Laura A. Rodriguez
lrodriguez@cassavasciences.com
Location: DocuSign

Signer Events	Signature	Timestamp
Laura A. Rodriguez lrodriguez@cassavasciences.com Senior Director, Clinical Quality Systems Cassava Sciences - Part 11 Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 593B4854-8E2E-4CA7-B255-9CBECDE6911E Using IP Address: 71.41.248.226 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I am the author of this document	Sent: 18-Oct-2023 | 14:51 Viewed: 18-Oct-2023 | 14:52 Signed: 18-Oct-2023 | 14:53
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Michael Marsman, Pharm D mmarsman@cassavasciences.com SVP, Regulatory Affairs Cassava Sciences, Inc. Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 6252303F-F961-490F-ACFF-567B84CF70BC Using IP Address: 73.158.252.185 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 18-Oct-2023 | 14:53 Viewed: 18-Oct-2023 | 16:08 Signed: 18-Oct-2023 | 16:08
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In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

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Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	18-Oct-2023 | 14:51
Certified Delivered	Security Checked	18-Oct-2023 | 16:08
Signing Complete	Security Checked	18-Oct-2023 | 16:08
Completed	Security Checked	18-Oct-2023 | 16:08

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

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